

### **REMARKS/ARGUMENTS**

By this Amendment, the specification is amended, claims 1-7, 9-11, and 13-17 are amended. Claims 18-28, 32 have been withdrawn from consideration pursuant to a restriction requirement. Claims 1-28, and 32 are pending. Claims 1-17 are under consideration.

Support for the amendments to the claims and Specification can be found throughout the Specification as filed, and specifically: Support for the amendment to the Specification can be found in originally filed claims 1, and 22-24; Support for the amendment to the claims for the limitation "mammalian" can be found on page 2, lines 20-25; support for the amendment to claim 6 can be found on page 3, line 27 to page 4, line 4.

Favorable reconsideration is respectfully requested in view of the foregoing amendments and the following remarks.

The Examiner's courtesy in granting an interview to Applicants' representative on January 22, 2009 is gratefully acknowledged. Applicants' separate record of the substance of the interview is incorporated into the following remarks.

#### **Specification**

The Examiner has objected to the Specification because at page 1, lines 27-29, the specification refers to claim numbers. Applicant respectfully traverses the foregoing objection. However, solely in an effort to expedite prosecution of the instant application, Applicant has amended the Specification to incorporate the text of originally filed claims referred to in the Specification. Reconsideration and withdrawal of the objection is respectfully requested.

#### **Rejection under 35 USC § 112 first paragraph**

Claims 1-17 stand also rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. This rejection is respectfully traversed.

The Examiner argues that while the level of ordinary skill in this art is at the postdoctoral level, without a substantive teaching of the starting material, the method cannot be enabled. The Examiner further argues that even if the starting material were considered to be exocrine tissue (i.e., not necessarily stem cells), the specification in view of the art is insufficient to enable the claims across their entire scope.

The Examiner argues that the art of isolating pluripotent stem cells from exocrine tissue and trans-differentiating these cells to yield pancreatic hormone-producing cells (i.e., endocrine

cells) must be considered "nascent," because a thorough search of the prior art found no such teachings at the time of the invention, so the amount of guidance required by applicant is relatively high. The Examiner further argues that only rat and human glandular tissue is employed in the working examples; there is no evidence that any tissue from an invertebrate could be used as the starting material for obtaining the pluripotent stem cells.

However, the test of enablement is whether one reasonably skilled in the art could make or use the invention from the disclosures in the patent coupled with information known in the art without undue experimentation. United States v. Teletronics, Inc., 857 F.2d 778, 785 (Fed. Cir. 1988). A specification disclosure which contains a teaching of the manner and process of making and using an invention in terms which correspond in scope to those used in describing and defining the subject matter sought to be patented must be taken as being in compliance with the enablement requirement of 35 USC 112, first paragraph, unless there is a reason to doubt the objective truth of the statements contained therein which must be relied on for enabling support. Assuming that sufficient reason for such doubt exists, a rejection for failure to teach how to make and/or use will be proper on that basis. In re Marzocchi, 439 F.2d 220, 224 (CCPA 1971).

Here, the claims are enabled because there is not any reason to doubt the objective truth of the statements contained in the Specification for enabling support. The Specification discloses the manner and process for making and using the claimed invention, including working examples which show the efficacy of the claimed invention. For example, the Specification provides clear guidance for the skilled artisan which steps are necessary to obtain pluripotent adult stem cells from different exocrine glands and different species. The Examples specifically disclose the isolation of stem cells from two species, namely human and rat, and from two tissue sources, namely acinar tissue of the pancreas (Example 2) and exocrine tissues (acinar tissue and tubular tissue) of the parotid gland (Example 3). In addition, Example 10 shows the insulin production of the differentiated cells with a microscopic image (see Figure 8) of insulin-producing cells that were obtained from the exocrine pancreas of a human being, and that corresponding results have been found with salivary glands of a human being or of other vertebrates.

Thus, the Specification provides clear guidance for the skilled artisan which steps are necessary to obtain pluripotent adult stem cells from different exocrine glands and different species.

Here, the Specification presents examples of pluripotent stem cells isolated from pancreas of human and rat, and that these cells have been shown to differentiate into insulin producing cells. The Specification teaches that the pancreatic stem cells can differentiate into nerve cells, glial cells, muscle cells, cartilage, exocrine glandular cells, endocrine glandular cells and epidermal cells. Thus, given the teachings of the Specification the quantity of experimentation required is not excessive in view of the subject matter of the claims. The Specification sets forth methods for producing IPAS cells. Working Examples are also provided, as well as detailed information as to the methods. This information can be used by one of ordinary skill in the art to determine appropriate solution conditions to practice the claimed process, without undue experimentation.

Accordingly, reconsideration and withdrawal of the rejection under 35 U.S.C. 112, first paragraph is respectfully requested.

**Rejection under 35 USC § 112 first paragraph**

Claims 1-17 stand rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. This rejection is respectfully traversed.

The Examiner argues that a stem cell has two properties: it can produce differentiated progeny, and it can renew itself (citing Potten et al.). A pluripotent stem cell can differentiate into many different cell types (citing MedlinePlus). The Examiner argues that for a cell to be considered a "pluripotential stem cell," evidence must show that it can give rise to at least two different mature cell types and that it is self-renewing, and the Examiner argues that such evidence is lacking in this application. The Examiner argues that the specification in view of the art fails to provide sufficient teachings that the skilled artisan would conclude that applicants possessed a method including obtaining bona fide pluripotent stem cells from exocrine tissue; therefore, the specification cannot enable methods of making pancreatic hormone-producing cells from exocrine tissue pluripotent stem cells.

To satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention. See, e.g., Moba, B.V. v. Diamond Automation, Inc., 325 F.3d 1306, 1319, 66 USPQ2d 1429, 1438 (Fed. Cir. 2003); Vas-Cath, Inc. v. Mahurkar, 935 F.2d at 1563, 19 USPQ2d at 1116. An applicant shows possession of the claimed invention

by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams, and formulas that fully set forth the claimed invention. Lockwood v. American Airlines, Inc., 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997). Possession may be shown in a variety of ways including description of an actual reduction to practice, or by showing that the invention was "ready for patenting" such as by the disclosure of drawings or structural chemical formulas that show that the invention was complete, or by describing distinguishing identifying characteristics sufficient to show that the applicant was in possession of the claimed invention. See, e.g., Pfaff v. Wells Elecs., Inc., 525 U.S. 55, 68, 119 S.Ct. 304, 312, 48 USPQ2d 1641, 1647 (1998); Eli Lilly, 119 F.3d at 1568, 43 USPQ2d at 1406; Amgen, Inc. v. Chugai Pharmaceutical, 927 F.2d 1200, 1206, 18 USPQ2d 1016, 1021 (Fed. Cir. 1991) (one must define a compound by "whatever characteristics sufficiently distinguish it").

Here, as set forth above, the Specification presents examples of pluripotent stem cells isolated from pancreas of human and rat, and that these cells have been shown to differentiate into insulin producing cells. The Specification sets forth methods for producing IPAS cells. Working Examples are also provided, as well as detailed information as to the methods. Thus, given the teachings of the Specification the patent Specification describes the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention. Applicant clearly has established possession of the invention that is now claimed.

Accordingly, reconsideration and withdrawal of the rejection is respectfully requested.

#### **Rejection under 35 USC § 112 second paragraph**

Claims 1-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. This rejection is respectfully traversed.

The Examiner sets forth that claim 1 requires obtaining pluripotent stem cells that "have a capacity to form organoid bodies," and argues that it is not clear whether claim 1 requires that organoid bodies be formed or simply that the cells obtained have the ability to form the same, and that the term "organoid bodies" is not clearly defined in the specification. Without acquiescing to the propriety of the Examiner's rejection, and solely to advance prosecution, claim

1 has been amended to remove the limitation "capacity to form".

The Examiner sets forth that claim 2 requires that "stem cells isolated primarily from the organism" be cultured, but it is not clear whether this claim attempts to further limit the cells of claim 1 or requires that a second population of stem cells be cultured. Without acquiescing to the propriety of the Examiner's rejection, and solely to advance prosecution, claim 2 has been amended to remove the limitation "primarily".

The Examiner sets forth that claim 4 is confusing because claim 1 does not require that the cells actually form organoid bodies, only that they have the potential to do so. Without acquiescing to the propriety of the Examiner's rejection, and solely to advance prosecution, claim 1 has been amended as set forth above.

The Examiner sets forth that the language in claim 5, specifically "stem cells isolated secondarily," is queried. Without acquiescing to the propriety of the Examiner's rejection, and solely to advance prosecution, claim 5 has been amended to remove the limitation "secondarily".

The Examiner sets forth that claim 6 is extremely wordy; it is not clear what active method steps this claim is intended to require. Without acquiescing to the propriety of the Examiner's rejection, and solely to advance prosecution, claim 6 has been amended herein to set forth the stimulating step.

The Examiner sets forth that claim 8 refers to "cellular imprinting," which is queried, and that generally, in cell biology, "imprinting" refers to epigenetic gene control in which certain nucleotides in a cell's DNA are modified, e.g. with a methyl group. However, the criteria for entering and sustaining a § 112, second paragraph rejection is stated in In re Moore, 169 USPQ 2361 238, (CCPA 1971) as:

Any analysis in this regard should begin with the determination of whether the claims satisfy the requirements of this second paragraph.

This first inquiry therefor is merely to determine whether the claims do, in fact, set out and circumscribe a particular area with a reasonable degree of precision and particularity. It is here where the definiteness of the language employed must be analyzed -- not in a vacuum, but always in light of the teachings of the prior art and of the particular application disclosure as it would be interpreted by one possessing the ordinary level of skill in the pertinent art.

Here, the Specification sets forth that (page 3, line 27 to page 4, line 4):

According to the invention the stimulation may comprise one or more of the following stimulation treatments that may be carried out simultaneously or successively. A treatment may be envisaged with supernatants of a primary culture of the endocrinal pancreas or of cell lines of the endocrinal pancreas, a co-cultivation with differentiated cells of the endocrinal pancreas or with cell lines derived from them, a treatment (imprinting) with immobilized or dissolved molecular differentiation factors provided in the liquid phase or a gene activation in the stem cell.

Thus, those skilled in the art would understand what is claimed when the claim is read in light of the specification.

The Examiner sets forth that claim 13 refers to "secretory glands," which is confusing allegedly because by definition, glands secrete bioactive agents. However, the term "secretory glands" is well-known in the art. For example, see U.S. Patent No. 5,885,971 (German et al.), which uses the term "secretory glands", and discloses that ('971, column 3, lines 60-65):

By "secretory gland" is meant an aggregation of cells specialized to secrete or excrete materials not related to their ordinary metabolic needs. Secretory glands include salivary glands, pancreas, mammary glands, thyroid gland, thymus gland, pituitary gland, liver, and other glands well known in the art.

Accordingly, in view of the case law cited above, the claims as presently before the Examiner, and the above explanations and/or arguments, it is respectfully submitted that the claims presently pending in this application comply in all respects with the requirements of 35 U.S.C. § 112, second paragraph and that the rejection based on this section of the patent statutes should be withdrawn.

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Application No. 10/561,628  
Amendment Dated 4/20/2009  
Reply to Office Action of 10/21/2008

For at least the reasons set forth above, it is respectfully submitted that the above-identified application is in condition for allowance. Favorable reconsideration and prompt allowance of the claims are respectfully requested.

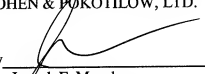
Should the Examiner believe that anything further is desirable in order to place the application in even better condition for allowance, the Examiner is invited to contact Applicants' undersigned attorney at the telephone number listed below.

Respectfully submitted,

CAESAR, RIVISE, BERNSTEIN,  
COHEN & POKOTILOW, LTD.

April 20, 2009

Please charge or credit our  
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